Fermilab

As-Is Baseline
Corrective Action Plan Report

June 15, 2009

Reviewed By: _____
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EXECUTIVE SUMMARY

The focus of this report is on Corrective Action Plans (CAPs) that were developed during the As-Is Baseline Assessment.

An assessment was performed between February 2 and April 30, 2009 to document the current, baseline implementation status of the Integrated Quality Assurance, and Integrated Contractor Assurance programs at Fermilab in accordance with its contractual commitments to the U.S. Department of Energy (DOE). Reference documents included DOE Order 414.1C *Quality Assurance*, and DOE Order 226.1A *Implementation of DOE Oversight Policy*. The focus of the assessment was the implementation status of the requirements contained in the Integrated Quality Assurance (IQA) and Integrated Contractor Assurance (FICAP) respectively. This assessment is referred to herein as the "As-Is Baseline Assessment" or "As-Is." The rationale for including both IQA and FICAP rests on the recognition of obvious overlaps between requirements contained in each and the synergies between the two programs.

The quality assurance program for scientific research will be assessed at a later time when the final Fermilab Guidelines for Scientific Research, developed to address the consensus standard ANSI/ASQ Z1.13 *Quality Guidelines for Research,* is published. At the time of this writing, this draft document is under peer review within Fermilab's scientific community.

The assessment was conducted under the direction of the Fermilab Office of Quality and Best Practices (OQBP) by selected Quality Assurance Representatives (QARs) and process owners from Fermilab Divisions, Sections and Centers (D/S/Cs) with the assistance of the on-site EG&G Quality Engineers (QAEs). An assessment subteam typically consisted of a QAR and a QAE in cooperation with a process owner for the area being assessed. The EG&G full time permanent QAEs were augmented by additional full time temporary QAEs to ensure that each QAR and process owner had sufficient professional QA support.

The project was managed by EG&G's Fermilab QA Manager (henceforth QA Manager). The full QAR team (QA Manager, QARs and QAEs) met frequently to maintain a data gathering and evaluation process that was as consistent as practical given the diversity of processes and activities being assessed. Weekly status reports and schedule updates were submitted to the QA Manager by each subteam. Standardized status reports provided cumulative status on processes assessed, processes remaining, CAPs planned, CAPs issued, non-consensus on evaluations and any obstacles encountered. Non-concensus items were elevated to the QA Manager.

D/S/C Heads received periodic briefs from their assessment subteam. Primary oversight was provided by the Head of OQBP and the EG&G Program Manager during periodic meetings. These meetings provided a summary of the project status and provided a forum for requests for intervention or additional resources. Secondary oversight was provided by the Fermilab Assurance Council which received periodic briefs on status from the OQBP staff (Head of OQBP, EG&G's Program Manager and the Fermilab QA Manager). The Laboratory Director was also given status briefings. Finally, the DOE Fermilab Site Office (FSO) was given regular IQA implementation status briefings.

The assessment reviewed a sufficient number of Fermilab major processes to give Fermilab management a baseline understanding of the current extent of compliance with requirements. The assessment also evaluated the Fermilab actions taken to correct the issues raised in the 2006 DOE Quality Assurance (QA) Audit and four associated risk areas identified in the audit findings related to document control, item control, control of measurement and test equipment (M&TE), and task specific qualification and training.

While details and enumeration of the processes assessed along with the full results of this assessment are documented in a separate As-Is Baseline Assessment Report, they indicate that many of the requirements of IQA and FICAP are being met either formally or informally. As indicated in the scope section of this report, there was no effort to make judgements about the effectiveness of the controls per se, but rather did they appear to meet requirements. However assessment results identified some areas that provide opportunities for improvement. As mentioned earlier, the focus of this report is on the Corrective Action Plans (CAPs) that were developed to address opportunities for improvement identified during this As-Is baseline assessment.

PURPOSE

As stated in the Executive Summary, the purpose of this report is to summarize the Corrective Action Plans (CAPs) that were developed to correct deficiencies or highlight opportunities for improvement identified during the As-Is Baseline Assessment and to describe how they were generated. The As-Is was conducted at Fermilab between February 2 and April 30, 2009 and resulted in the generation of 98 CAPs.

The As-Is was performed to determine how many of the requirements of Fermilab's IQA and FICAP, respectively, are currently being satisfied by the Laboratory. The assessment also evaluated the status of the actions taken to correct the DOE 2006 QA audit issues and included a special review of four associated risk areas.

SCOPE

The scope of this assessment was bounded by two conditions; 1) the sample of significant Fermilab processes assessed and 2) the depth of assessment.

1. Fermilab D/S/C's identified significant processes which are in place to carry out the scientific mission and operating business of the laboratory. From this large "universe" of candidates for assessment QARs and D/S/C heads selected a sample of processes for evaluation based on a number of criteria including; known (or unknown) risk, importance to the operation of the laboratory, whether the process is subject to external review by DOE, FRA or other parties and their importance to QA compliance. A key consideration was how the process assessed represented other supporting processes such that the results could reasonably be ascribed to those other processes not singled out for assessment. Nevertheless, it is noted that the assessment covered only a sample of the laboratory's processes and was the result of judgement. Processes assessed by each D/S/C are identified in a separate final As-Is Baseline Assessment report.

2. The scope was further bounded by the depth of assessment. While the teams were trained in formal QA auditing methodology and utilized skills obtained from that training, they were restricted primarily to determining what controls were in place for each process assessed and whether those controls appeared to satisfy the requirements of IQA and FICAP. There was no effort to make judgements about the effectiveness of the controls per se, but rather did they appear to meet requirements.

   It is also understood that all of Fermilab's processes are subject to formal QA assessment when the Fermilab assessment program is fully implemented, and that many or all of the processes evaluated during the As-Is will also be subject to formal QA assessment at that time.

BACKGROUND

A number of activities are required to implement Fermilab's approved IQA program. Many of these activities have already been undertaken or completed such as; assigning and training QAEs and QARs from each D/S/C, informing management and staff about the new IQA program and

the Graded Approach procedure, developing tools for communication and data gathering and so on. The next activities were to obtain a baseline understanding of where the laboratory stands in relation to the requirements of the IQA and FICAP programs, to determine the gaps between the initial baseline and where the laboratory needs to be, and to issue CAPs to bridge these gaps.

When all As-Is activities including reporting and data management are complete, data gathered during As-Is will be frozen as read only. Since the completion of the As-Is the site's focus has transitioned to closure of the CAPS. In parallel with CAP closure, Fermilab is developing a Fermilab Consolidated Assessment Program and releasing a Graded Approach Tool to support the Graded Approach Procedure for QA.

PHASES OF THE AS-IS PROCESS

There were five phases applied iteratively to each process assessed during the As-Is:

- ***Initiation Phase***
    - Schedule initial informational / planning meeting(s) with process owners, subject matter experts and/or appropriate departmental management

- ***Development Phase***
    - Use preliminary meeting information to understand process and plan Collection Phase

- ***Collection Phase***
    - Document processes and their quality controls
        - Integrate 2006 DOE QA audit as applicable
            - Verify closed items
            - Assign open items
    - Return and complete evaluation of process quality controls
    - Enter data into the As-Is tool translating into QA program language
    - Identify potential gaps in quality controls

- ***Verification Phase***
    - Verify the accuracy of data entered into the As-Is tool with process owner
    - Review the evaluation of controls (comparison with expected controls), and gaps identified with process owner with an eye to consensus
    - Agree on the need to issue CAPs
        - Record when consensus was not reached

- ***Corrective Action Phase***
    - Develop and document CAPs to bridge agreed upon gaps (Process Owner)
    - Approve CAPs and forward to the Head of OQBP for concurrence (D/S/C Head)
    - Track & report status of CAPs locally (QAR & Process Owner)
    - Review the approved CAPs, reconcile differences, and concur (OQBP)

- Verify closure of CAPs as they are completed (QAEs & Quality Manager)
- Track and report status of CAPs globally (Quality Manager & OQBP Head)
- Periodically validate CAP implementation effectiveness

AS-IS CORRECTIVE ACTION PROCESS DESCRIPTION

CAPs were initiated and issued during the last two phases of this process. The Fermilab Corrective Action Procedure was followed during the As-Is, and a CAP form was tailored to accommodate the steps of the Corrective Action Phase. This ensured that signatures were obtained from process owners, D/S/C Heads, and the Head of OQBP signifying commitments, approvals and concurrence respectively.

CAP Drafting & Development

QARs drafted a CAP for each non-compliance or opportunity to improve. CAP forms were generated in accordance with the Fermilab Corrective Action Procedure (See Appendix 1). Each received a unique number for tracking purposes. The problem to be addressed was identified and the CAP reviewed with the responsible process owner, or designee, who signified acceptance by signing and dating the acceptance section of the form. The process owner indicates the problem to be addressed, the root cause of the problem, and the required actions (remedial, corrective and/or preventive), timeline for implementation, and who will complete the work by completing and signing the development section of the form.

Non-consensus

When consensus could not reached between the process owner, QAR and QAE regarding the need to issue a CAP it was documented and treated as a dissenting opinion in accordance with Section 10.1 of the FICAP. The QA Manager negotiated with the process owner, QAR and QAE to resolve any non-consensus. This was required in only one instance and the CAP was withdrawn as more information indicated an adequate level of compliance. All non-consensus items and their status were reflected in the cumulative As-Is status report for each D/S/C.

CAP Approval & Concurrence

All CAPs generated during the As-Is were forwarded for approval and commitment of resources to the D/S/C Head and from the D/S/C Head to the QA Manager for concurrence by the Head of OQBP. During his absence the Head of OQBP granted signature authorization to the QA Manager for CAPs where concurrence was achieved without the need for elevation to a higher level.

Non-concurrence

When the QA Manager did not agree with proposed corrective actions he briefed the Head of OQBP and solicited advice. Typically the QA Manager would meet with the affected parties and recommend acceptable paths to concurrence beginning with the QAR and QAE followed by the QAR's management, if necessary. If this was unsuccessful the head of OQBP negotiated directly with the head of the D/S/C to an acceptable conclusion. Although further intervention was not required in any of the current CAPs, the defined next step was elevation to the Assurance Council and if necessary to the Laboratory Director for final disposition.

Cap Tracking

As noted above, all CAPs received a unique tracking number. They are tracked by the issuing QAR and by the QA Manager from initiation through implementation, verification by the responsible QAE and closure. The As-Is Baseline assessment was an OQBP initiated assessment. The CAP form indicates that for assessments initiated by OQBP, QAEs verify, and if necessary validate, CAP implementation.

Cap Reviews

Several levels of reviews were held for each CAP:

- Initial draft by the responsible QAR and QAE for accuracy and completeness
- QAR, QAE and process owner sub-team for accuracy, completeness and relevance
- Issued CAPs by the QA Manager for accuracy, completeness, relevance, consistency, and trending by category (usually criteria or requirement)
- Full QAR team for accuracy, completeness, relevance, consistency, trending by category and for possible consolidation or elevation (or both)
- OQBP for overall acceptability
- OQBP for possible elevation to the Assurance Council

Cap Disposition & Assignment

After the above listed reviews, CAPs were dispositioned in one or more of the following ways:

- Implement and assign within the responsible D/S/C as written
- Consolidate with one or more CAPs to eliminate redundancy
- Consolidate with one or more CAPs for possible elevation to the Assurance Council
- Elevate lab-wide issue to the Directorate by the Assurance Council
    - Decision to elevate by full QAR team consensus
    - Elevation to OQBP as AC secretary
    - Presentation to the Chairman of the AC by OQBP
    - Elevation with recommended assignment to the full AC by the Chairman

Elevation could be terminated at any point in the above process.

Criteria for elevation included:

- Ubiquity - frequency throughout the laboratory
- Consistency – a lab-wide solution may be required to maximize effectiveness
- Cost – a lab-wide solution may be required to minimize total cost
- Risk – potential impact of the item is high and may be lab-wide
- Ownership – requires change by external process owner
- To-Be – required document or program not yet developed or approved
- Legal – potential liability requiring review by General Counsel

CAP RESULTS SUMMARY

CAP Results Combined

CAP Summary by Category as of 06/04/09

Table 1 - Pivot Table

	Count of Category	
	Category	Total
*	Assessments	4
*	Documents	34
	Inspection / Test	1
	Item Control	1
*	M&TE	8
*	PII	1
*	Qualification & Training	13
*	Records	14
	S/CI	1
	Work Processes	2
	Design	1
*	Requirements Flowdown	1
	Quality Improvement	1
*	Program	10
**	Grand Total	92

Table 2 - Sort on Frequency

	Count of Category		
	Category	Total	% of Total
*	Documents	34	36.96%
*	Records	14	15.22%
*	Qualification & Training	13	14.13%
*	Program	10	10.87%
*	M&TE	8	8.70%
*	Assessments	4	4.35%
	Work Processes	2	2.17%
	Inspection / Test	1	1.09%
	Item Control	1	1.09%
*	PII	1	1.09%
	S/CI	1	1.09%
	Design	1	1.09%
*	Requirements Flowdown	1	1.09%
	Quality Improvement	1	1.09%
**	Grand Total	92	100.00%

* 19 of 98 elevated to OQBP

** Excludes 6 Cancelled CAPs (duplicate elevations etc)

** 71 CAPs accepted by Process Owners others in progress (excludes elevated & cancelled)

Table 1 above is a summary pivot table sorted alphabetically by category (default) in Microsoft Excel™. Table 2 shows the same results, sorted manually in pareto order that is, from largest frequency (and %) to smallest. This allows management to quickly see the QA / CA criteria and requirements categories in perspective. In both tables items with an asterisk (*) include CAPs that were elevated to the AC. In order to minimize confusion and double counting of CAPs, they were only assigned to the one most relevant category rather than to multiple categories; although in some cases there may have been overlap. Some interesting results have emerged viz:

- Elevated items are, with two exceptions, also in the top five highest frequencies. The two exceptions were both high potential impact (PII, and Requirements Flowdown) although combined they represent only about 2% of CAPs issued. These exceptions are singled out and given their own categories for this reason.

- Elevated items are, with one exception (Item Control), also included in the four risk areas which received special review (Task Specific Qualification & Training, Documents & Records, Item Control and Control of Measurement & Test Equipment [M&TE]). A preliminary review of the draft report on Item Control did not allow us to reach the conclusion that an elevated CAP was required.

- The top six CAP frequencies, in addition to being elevated, also appeared as findings in DOE's report from the 2006 Fermilab QA Program Assessment. While not necessarily the same specific cases in the same organizations, they were in the same categories of CAPs. The As-Is confirmed the existence of the same kinds of issues reported to Fermilab by the DOE 2006 QA assessment team as being present in other areas of the laboratory that were not directly assessed at that time.

- Nine of the ten CAPs in the category Program were written for completion of required To-Be Documents.

Analysis of CAP Results

The following table provides a summary of the CAPs for each Fermilab D/S/C assessed during the As-Is. A summary with details of these assessments are provided in the As-Is Baseline Assessment Report.

CAP Summary by D/S/C & Category as of 06/04/09

Table 3 - Pivot Table

Count of D/S/C	D/S/C										
Category	AD	BSS	CD	ESH	FES	FI	OQ	PP	TD	WDR	Grand Total
Assessments		1		1			1			1	4
Design	1										1
Documents	2	4	1	2	4	1	2	3	9	6	34
Inspection / Test									1		1
Item Control									1		1
M&TE	1		1	1			1	1	3		8
PII							1				1
Qualification & Training			1		1		2	6		3	13
Quality Improvement								1			1
Records	1		1	2	1	1	1	2	1	4	14
Requirements Flowdown							1				1
S/CI									1		1
Work Processes	1	1									2
Program							10				10
Grand Total	6	6	4	6	6	2	19	13	16	14	92

* 19 of 98 elevated to OQBP

** Excludes 6 Cancelled CAPs (duplicate elevations etc)

** 71 CAPs accepted by Process Owners others in progress (excludes elevated & cancelled)

Table 3 above is a summary two-way pivot table sorted alphabetically by category and by D/S/C (default) in Microsoft Excel™. This is the same data set presented in Tables 1 and 2 earlier but partitioned differently. Care must be taken not to over analyze these results or conclude from the numbers posted that one area assessed was necessarily more or less compliant that others. While it may be an interesting exercise to analyze these results using non-parametric (categorical) statistical methods the effort may result in misleading conclusions especially since such analyses are typically most successful when applied to data gathered from a statistically designed experiment, survey or sampling scheme, none of which is the case here. The sampling of processes was subject to judgement based on a number of criteria with different degrees of applicability to those selecting the processes for assessment. These results were also obtained using judgement applied to facts by persons trained to do so but with a wide range of applied experience. As discussed in the scope statement, although the teams were trained in formal QA auditing methodology and utilized skills obtained from that training, they were restricted primarily to determining what controls were in place for each process assessed and whether those

controls appeared to satisfy the requirements of IQA and FICAP. There was no effort to make judgements about the effectiveness of the controls per se, but rather did they appear to meet requirements. The absence of multiple CAPs in any particular category is as likely to be due to the absence of assessment of effectiveness as it is due to the other variables discussed regarding Tables 1 and Tables 2.

Despite all attempts to perform in as unbiased and as consistent a manner as possible, including regular full QAR team meetings, standardized checklists, tools and so on; these results were likely influenced by many factors. For example, each area was assessed by a different team with different background experiences and skills, conducted in different operating environments in areas with very diverse missions, processes, process owners, management and procedures, as well as being in areas regulated more or less closely than each other. The area with lowest number of CAPs is simultaneously the area with the fewest number of processes assessed which is likely the most highly regulated by various offices of the DOE. It does not necessarily follow from this that each of the areas with the three largest numbers of CAPs must be the least scrutinized or regulated. In addition a CAP for the category Documents may have significantly more impact in one area than two or more combined for the same category in a different area. For instance the latter deficiency could be administrative in nature and low in impact based on the kinds of activities the document is intended to specify or control, while the former could be just the opposite in impact. The only thing that can be held in common for each CAP issued is that the teams and process owners undertook each assessment with the same degree of diligence using the same methods and tools as consistently as practicable and issued each CAP with the same spirit of continual improvement within Fermilab.

Elevated CAP listing

Elevated CAP #	**Category**	**Drafted by**	**Problem/Opportunity To Be Addressed / Comments (Summarized)**
OQ-04/27/09-01	Records	Jed Heyes	The BSS Records Management Policies and Procedures, which implement DOE contractual requirements, are applicable Fermilab wide, yet are not reflected in the Fermilab Director's Policies.
OQ-05/04/2009-1	Documents	Jed Heyes	The Fermilab Policies listed in Section 3 of the Fermilab Policy Manual (aka Director's Policy Manual) do not achieve its intended purpose stated in Section 1 which paraphrased is: 1. assure appropriate flowdown, & 2. provide for consistent review and interpretation of DOE directives, Federal, State and local laws and regulations
OQ-05/04/2009-2	Assessments	Jed Heyes	The Fermilab Director's Policy #20 does not provide D/S/C line management with the necessary guidance on which kinds of assessments are to be planned, conducted, and reported by D/S/C's. This should be in DP#20 an Assessments program document or both.
OQ-05/04/2009-3	PII	Jed Heyes	The Fermilab Director's Policy #38 Personally Identifiable Information (PII) has an effective date of 4/26/2007 and the Fermilab Procedures for Protected PII states that "All lab systems must be brought into compliance with the procedures by July 1, 2007, but they were not fully implemented at the time of the As-Is assessment of WDRS in April, 2009".

Elevated CAP #	Category	Drafted by	Problem/Opportunity To Be Addressed / Comments (Summarized)
OQ-05/06/2009-1	Qualification & Training	Jed Heyes	There needs to be a general lab-wide awareness activity for the Director's Policy Manual, IQA and FESHM as many individuals interviewed across the lab knew little about these documents, where they are, and what they contain, although FESHM was more widely known for activity specific areas.
OQ-05/06/2009-3	M&TE	Jed Heyes	IQA 8.5 Measurement and Test Equipment are not consistently implemented across the D/S/C.
OQ-05/06/2009-4	Qualification & Training	Jed Heyes	Fermilab needs to provide employee training to specifically address Quality Assurance in compliance with Director's Policy #19 on Training.
OQ-05/06/2009-5	Requirements Flowdown	Jed Heyes	Fermilab lacks a systematic procedure for ensuring that all requirements are flowed down to the lowest level appropriate.
OQ-05/06/2009-6	Documents	Jed Heyes	Director's Policy #13 on Document Control needs to be more specific as to which documents it applies to and which kinds of documents are out of scope.
OQ-05/22/2009-1	Program	Jed Heyes	IQA section 6.2.1 identifies responsibilities for a Fermilab Chief Engineer. Although the IQA was approved by the Fermilab Director in October 2008, and by the Fermilab Site Office for DOE in November 2008, a Chief Engineer has not yet been named
OQ-05/22/2009-2	Program	Jed Heyes	IQA section 6.1 refers to a To-Be Fermilab Design & Engineering Processes Manual (FDEPM). Although the IQA was approved by the Fermilab Director in October 2008, and by the Fermilab Site Office for DOE in November 2008, the FDEPM document has not been published.
OQ-05/30/2009-1	Program	Jed Heyes	IQA Chapter 9 contains numerous references to a To-Be [Fermilab Assessments Manual]. Although the IQA was approved by the Fermilab Director in October 2008, and by the Fermilab Site Office for DOE in November 2008, this document has not been published.
OQ-05/30/2009-2	Program	Jed Heyes	FICAP 9.1 refers to a To-Be [IMS Issues Tracking Procedure]. Although the FICAP were approved by the Fermilab Director in October 2008, this document has not been published since it was separated from the Fermilab Corrective Action Procedure.
OQ-05/30/2009-3	Program	Jed Heyes	FICAP 7.3 refers to a To-Be [Lessons Learned Program] document. Although the FICAP were approved by the Fermilab Director in October 2008, this document has not been published.
OQ-05/30/2009-4	Program	Jed Heyes	Both IQA 3.3.2 and FICAP 5.4 refer to a To-Be [Management Review Procedure]. Although both the IQA & FICAP were approved by the Fermilab Director in October 2008, and IQA by the Fermilab Site Office for DOE in November 2008, this document has not been published.
OQ-05/30/2009-5	Program	Jed Heyes	IQA 3.3.4 refers to a To-Be [Root Cause Procedure]. Although the IQA was approved by the Fermilab Director in October 2008, and by the Fermilab Site Office for DOE in November 2008, this document has not been published.
OQ-05/30/2009-6	Program	Jed Heyes	IQA Chapter 10 refers to the draft Suspect/Counterfeit Items Program document. Although the IQA was approved by the Fermilab Director in October 2008, and by the Fermilab Site Office for DOE in November 2008, this document has not been formally approved and published.

Elevated CAP #	Category	Drafted by	Problem/Opportunity To Be Addressed / Comments (Summarized)
OQ-05/30/2009-7	Program	Jed Heyes	IQA Chapter 11 refers to a To-Be [Director's Policy on Scientific Research]. Although the IQA was approved by the Fermilab Director in October 2008, and by the Fermilab Site Office for DOE in November 2008, this document has not been published. Director's Policy #9 on Experiments/User's Identification only addresses ID badges.
OQ-05/30/2009-8	Program	Jed Heyes	IQA Chapter 11 refers to a To-Be [Quality Guidelines for Scientific Research at Fermilab]. Although the IQA was approved by the Fermilab Director in October 2008, and by the Fermilab Site Office for DOE in November 2008, this document has not been published.

As-Is Assessment Results

Detailed results of the As-Is are provided in a separate document, the As-Is Baseline Assessment Report. This report makes no attempt to discuss broader results obtained such as how many, and which areas were deemed to be fully implemented, partially implemented, not implemented or not applicable. It focuses on summarizing the area's where CAPs were issued and what kinds of CAPs where issued.

2006 DOE QA Program Assessment Finding Closure Review Results

The actions taken to correct the issues identified in the specific 2006 DOE QA Program Assessment (hereafter "audit") findings were reviewed to determine if they are sufficient to resolve the DOE findings. The focus of that review was on the adequacy of how each finding reported was addressed. Results of that review are also summarized in the As-Is Baseline Assessment Report. Twenty-six CAPs were issued for "Observations of Less than Adequate Implementation" during this assessment. Each CAP was assigned to the responsible process owner and tracked or elevated to the AC to be tracked in the Fermilab Issues Management System or both. At the time of this writing, reconciliation of the As-Is assessment in this area is still being compiled and reviewed.

Review of Risk Areas

Senior management identified four areas of potential risk. During this assessment these areas were emphasized within each D/S/C.

The four major risk areas selected were; task-specific qualification and training, control of documents and records, item control, and control of measuring and test equipment (especially calibration of this equipment). To ensure this was adequately covered each As-Is assessment team included these areas within the scope of their data gathering and evaluation. In addition, a QAE was assigned to review and evaluate all the results for one or more of these risk areas and to provide an independent and separate draft summary report to the QA Manager. Results of that review are intended to provide some level of assurance as to the state of the entire laboratory in those categories and are also summarized in the As-Is Baseline Assessment Report. As discussed earlier there are elevated CAPS for all but one of these risk areas, and at least one CAP for each risk area. At the time of this writing no additional CAPs have been generated from these draft risk area reports. This does not preclude that possibility after further review at a later date. At the time of this writing, reconciliation of the As-Is assessment in these areas is still being compiled and reviewed.

Fermilab's Plan to Bridge Gaps Identified During the As-Is

Fermilab management is committed to bridge the gaps between the As-Is and To-Be states by implementing the following actions:

Continuing Steps of the Corrective Action Phase

- Approve CAPs and forward to the Head of OQBP for concurrence
- Implement approved CAPs & report status to QARs / QA Manager
- Verify closure of CAPs as they are completed
- Track and report status of CAPs globally
- Periodically validate CAP implementation effectiveness

It is anticipated that all CAPs will be approved and all corrective actions either completed or in progress before the week of September 14, 2009 in preparation for the upcoming assessment of Fermilab's QA implementation by DOE.

APPENDIX 1

SUBJECT:	Fermilab Corrective & Preventive Action Plan – Form 1 - Simple	NUMBER:	1004.1001 FORM 1
RESPONSIBILITY:	Quality Assurance Manager	REVISION:	000 C3
APPROVED BY:	Head, Office of Quality and Best Practices	EFFECTIVE:	04/03/09

CAP INITIATION

This section to be completed by the person requesting simple corrective / preventive action
Requestor Name: [ ] **Organization:** [ ] **Phone:** [ ]
Problem/Opportunity To Be Addressed: [ ]
Unique Tracking Number: DD-MM/DD/YYYY-x: [ ] **(DD=Div or Sec, MM/DD/YYYY= Date Opened, x=1, 2, …n)**
Responsible Person: [ ] **Organization:** [ ] **Phone:** [ ] ****Responsible Person Acceptance:** [ ] **Date:** [ ]
***Comments:** [ ]

CAP DEVELOPMENT

This section to be completed by the Responsible Person
Describe the Actual Problem/Opportunity, and What Caused it (Simple Root Cause): [ ]
Remedial/Compensatory, Corrective, and/or Preventive, actions being taken and (where applicable) Initial Lessons Learned: [ ]
Planned start date (format MM/DD/YYYY): [ ] **Key milestones and Dates:** [ ] **Estimated date for completion:** [ ]
Who will complete the work, [ ] **Phone:** [ ] **Who will perform verification and/or validation,** [ ] **Phone:** [ ]
****Responsible Person:** [ ] **Date:** [ ] ***Comments:** [ ]

* Optional field **Signature *** Required only for OQBP initiated assessments Page 1 of 2

SUBJECT:	Fermilab Corrective & Preventive Action Plan – Form 1 - Simple	NUMBER:	1004.1001 FORM 1
RESPONSIBILITY:	Quality Assurance Manager	REVISION:	000 C3
APPROVED BY:	Head, Office of Quality and Best Practices	EFFECTIVE:	04/03/09

CAP APPROVAL, & CONCURRENCE

This section to be completed and signed by persons identified below	
** Approval Head D/S/C: [ ]	Date: [ ]
*Comments: [ ]	
***OQBP Concurrence: [ ]	Date: [ ]
*Comments: [ ]	

CAP CLOSURE

This section to be completed and signed by persons identified below	
Description of actions taken to implement: [ ]	
**Implemented By: [ ]	Date: [ ]
**Verified By: [ ]	Date: [ ]
*Comments: [ ]	
** Acceptance Requestor: [ ]	Date: [ ]
*Comments: [ ]	
**Acceptance Head D/S/C: [ ]	Date: [ ]
*Comments: [ ]	

See Fermilab Corrective Action Plan Guide to Form 1 for directions and a completed example

* Optional field **Signature *** Required only for OQBP initiated assessments Page 2 of 2

Table of Revisions

Author	Description	Revision	Date
Jed Heyes	Draft- Updated with iterative OQBP staff reviews	000 A-A15	04/09/09 – 06/05/09
Jed Heyes	Final OQBP review updates	000 B	06/05/09
Jed Heyes	Minor spelling corrections & release for approval	000 C	06/05/09
Jed Heyes	Minor spelling corrections	000.1 C	06/06/09
Jed Heyes	Updated title page	000.2 C	06/08/09